Testimony of
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On Behalf of Medical Imaging & Technology Alliance (MITA)

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Committee on Energy & Commerce
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Hearing on
Discussion Draft of the "Food and Drug Administration Globalization Act"
Legislation: Device and Cosmetic Safety Provisions

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Mr. Chairman, Chairman Dingell, Ranking Member Barton, Ranking Member Deal and Members of the Committee, thank you for the opportunity to testify before the Committee today on the important topic of the Food and Drug Administration's (FDA) inspections of foreign manufacturing facilities. My name is Elisabeth George, Vice President, Quality, Regulatory, Sustainability & Product Security of Philips Healthcare. I am testifying today on behalf of the Medical Imaging & Technology Alliance (MITA) where I serve as a Member of the Board of Directors. MITA is the collective voice of medical imaging equipment manufacturers, innovators, and product developers. It represents companies whose sales comprise more than 95 percent of the global market for medical imaging technology. Medical imaging encompasses X-ray imaging, computed tomography (CT) scans, radiation therapy, diagnostic ultrasound, nuclear medical imaging (including (PET)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with serious diseases including heart disease, cancer and stroke, often reducing the need for costly medical services and invasive surgical procedures.[1] In addition, medical imaging equipment is often used to facilitate effective treatment, for example, by guiding physicians as they carry out a medical or surgical intervention, to ensure high-quality clinical results for the patient.[2]

MITA represents large, mid-size and small manufacturers who manufacture and conduct most of their research and development right here in the United States. The medical imaging industry is

[1] Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., New England Journal of Medicine, Vol 352, No 17; pp1760-1768, April 28, 2005. Further, in reviewing the clinical literature, MITA recommends that CMS consider the positive findings on the cost-effectiveness of PET in the diagnosis of lung cancer. Muller A., Stratmann-Schone D, Klose T, Leidl, Overview of Economic Evaluation of Positron-Emission Tomograpy. Eur J Health Econ 3:59-65 2002.

[2] Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731 - 737.

a net exporter and a positive industry for the U.S. economy. Our industry employs tens of thousands of skilled workers here in the U.S. The research and development that led to the innovative technologies such as magnetic resonance imaging MRI, CT and PET, which detect, and are instrumental to the treatment of, serious illnesses, were invented in the U.S.

Importance of Medical Imaging

MITA applauds and appreciates the support from leadership and members on this Committee to protect medical imaging from further reimbursement cuts. Medical imaging empowers doctors and medical professionals to view the human body with ever increasing clarity and accuracy. This enables better diagnoses and more effective medical care for patients. In addition, medical imaging is integral to best practices across many disease states. It is essential to the continuum of care – from prevention, to diagnosis, to treatment –and the result is improved outcomes for patients. In fact, the *New England Journal of Medicine* has acknowledged the value of medical imaging, calling it **one of the top 11 innovations of the past 1,000 years**. Medical imaging allows for less invasive, highly-targeted medical surgeries and therapies that translate to shorter hospital stays, fewer complications, and greater comfort for patients.

Medical imaging is essential to many widely-accepted quality and screening guidelines for a variety of diseases, including breast cancer. For example, the American Cancer Society recommends that every woman 40 years old and older receive an annual mammogram. In fact, when breast cancer is detected early, while still confined to the breast, the five-year survival rate increases to more than 98 percent. Consequently, these devices help millions of Americans more effectively fight and survive serious illnesses such as breast, ovarian, cervical, colorectal, lung

and prostate cancers, heart disease and osteoporosis. Detecting these critical illnesses at their most curable stage is essential. Medical imaging saves money – by reducing or eliminating unnecessary surgery and post-operative care. It also often replaces more costly tests or treatments. CT scans, for example, have all but eliminated the practice of exploratory surgery with its associated risks and lengthy recovery periods.

The Device Industry is Highly Regulated Both Domestically and Internationally

We understand that there are significant concerns about drug ingredients and food that have been imported from foreign countries. However, we believe the device industry, a highly regulated industry globally, is vastly different. Before we turn to the specific differences between drugs and devices, it is important to note that not all devices are the same.

Regulatory Classification of Devices Based on Risk

FDA's Center for Devices and Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States. Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III based on the level of risk. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.

Device classification depends on the *intended use* of the device and also upon *indications for use*. For example, a scalpel's intended use is to cut tissue. A subset of intended use arises when a more specialized indication is added in the device's labeling such as, "for making incisions in

the cornea". Indications for use can be found in the device's labeling, but may also be conveyed orally during sale of the product. A discussion of the meaning of intended use is contained in Premarket Notification Review Programs.

In addition, classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk, Class II with moderate risk, and Class III includes those with the greatest risk. Medical imaging and radiation therapy devices are Class II devices that require filing a 510(k) to demonstrate that they are substantially equivalent to a predicate device, but are not considered high risk. As a result, when FDA considers its inspectional priorities, if a manufacturer of a Class II device has a good inspectional history, they receive inspections less frequently. According to the Government Accountability Office (GAO), domestic manufacturers of Class II devices are inspected on average of once every 5 years. However, at Philips Healthcare and at other imaging device manufacturers, inspections occur on a much more frequent basis, in spite of our excellent inspectional history and low relative product risk.

Global Inspection Process

MITA members' foreign and domestic manufacturing facilities are subject to international quality and safety inspections **at least annually** as part of the International Standards Organization (ISO) 13485 standard, a standard virtually identical to FDA Quality System Regulations (QSR). Meeting the ISO 13485 standard is a requirement for medical imaging manufacturers in 47 countries and all major regulatory agencies worldwide[3].

[3] List of countries attached as Appendix A

The slight differences between FDA's QSR and the ISO 13485 standard fall into four categories. However, the spirit and substance of the requirements are the same.

- **Recall regulations** – As part of the Corrective and Preventive Action (CAPA) regulations present in QSR and ISO, FDA may also follow up on product recalls. However, recall reporting is mandated outside the inspection requirements (as part of 21 CFR 806) and requires separate reporting by manufacturers to FDA. FDA may follow up on these at any time; inspections are not needed to enforce these requirements.

- **Medical Device Reporting (MDR) regulations –** As a follow up to certain complaints, FDA may evaluate the manufacturer for their MDR content. However, the MDR requirements are not managed by the inspection process (actually part of 21 CFR 803) and require direct reporting to the agency.

- **Design History Files –** Design History Files include information on how a product was developed by a company. Both the ISO and QSR require this information to be maintained for inspection. The same information is required, but the terminology varies slightly.

- **Device History Records –** Device History Records include information on how a product is manufactured and show that specific quality assurance steps are taken in the manufacturing process. The ISO and QSR requirements for Device History Records are

virtually identical. But similar to the regulations for Design History Files, the only difference is in the terminology used.

MITA believes that the FDA should avail itself of the valuable information gained from these inspections that are already required by every other industrialized nation. Beyond these four minor points, the remaining variations between the QSR and ISO 13485 entail definitions of terms and other minor wording differences. Indeed, as the FDA is intricately involved in the development of the ISO standards, FDA should be able to readily adopt the ISO 13485 quality system standard as the basis for its regulatory process.

Drugs v. Imaging Devices

As opposed to drugs, medical imaging devices are inspected and approved by the FDA as finished products. Component parts for devices, that include screws, circuit boards and screens must work correctly for the completed device to function properly and pass its rigorous inspections. Each component part must meet stringent individual international standards that are established by regulatory bodies. While we understand the concern over component drug ingredients, in the medical imaging industry, if components do not function correctly, the device does not operate properly. Imaging devices are tested throughout the production process and in final inspection. Any malfunctioning that may arise as a result of faulty component parts is identified during mid-product testing or in the testing of finished devices.

The FDA's inspection process and the international regulatory structure for devices are both based on the fact that a properly designed and implemented quality system will ensure quality of

components for the finished product to operate correctly. Examining component parts would be duplicative, unnecessary and not be a prudent use of FDA resources in this arena. Requiring the inspection of each component part is a wholesale change in the way imaging devices are regulated by the FDA currently and could grind manufacturing to a halt.

Food & Drug Administration Amendments Act of 2007 and User Fees

The Food & Drug Administration Amendments Act of 2007 (FDAAA) was the result of a carefully crafted negotiation between FDA and industry that resulted in providing much needed resources to the FDA. FDAAA represented an increase of nearly 90% in user fees to the industry over 5 years. User fees went from approximately $150 million to nearly $300 million from the original Medical Device User Fee Amendments (MDUFMA) to FDAAA. The industry agreed on the increase in order to provide stability to the agency and ensure that life-saving medical devices would proceed to market. There is a shared goal by the FDA and industry to provide new resources to the FDA so that innovative products can be expeditiously reviewed and patients can continue receiving access to critical diagnosis and treatment equipment.

FDAAA also included, for the first time, an annual fee of $1700 per facility (domestic and foreign) as part of a carefully negotiated compromise to bring needed resources into a specific part of the agency, FDA's Center for Devices and Radiological Health (CDRH). The new fees included in the Discussion Draft provide no obvious link to the FDA's work on medical devices. In addition, these new fees unfairly burden domestic medical imaging manufacturers, which comprise 52 percent of the global market. The effectiveness of added fees is questionable, given

that over 90 percent of medical imaging and oncology treatment devices are manufactured in industrialized nations such as the U.S., European Union, and Japan.

As part of the FDAAA, manufacturers (both domestic and foreign) and initial distributors (importers) of medical devices must register their establishments with the FDA. All establishment registrations must be submitted electronically unless a waiver has been granted by FDA.

It is important to note that FDAAA also included statutory revisions to the third-party inspection program which is intended to increase participation while maintaining all of the stringent conflict of interest requirements. As a result, Philips Healthcare has signed up for 22 new third-party inspections. Prior to the modifications we had conducted two inspections. These third party inspections we believe will achieve the goal, much as the Committee has done in the Food section of this Discussion draft, of providing a greater window of transparency into the inspection process and get more inspection information to the FDA. In order to participate in the program, a manufacturer needs to have a good inspectional record conducted by the FDA.

FDA Globalization Bill

MITA understands the Committee's desire to ensure that FDA is well funded and that medical products imported into the United States are safe for U.S. patients. However, MITA has a number of concerns about the FDA Globalization Bill discussion draft. As mentioned above, we do not believe the bill takes into account the unique nature of medical devices, specifically how they are regulated and manufactured. In summary, MITA's concerns are as follows:

- The Discussion Draft would require an FDA inspection for each "minor modification" in a medical device prior to importation into the U.S. MITA believes this inspection requirement will unduly stall delivery of improved technology into the U.S. market. On average, each medical imaging device is updated with improved technology once every 18 months. For example, a manufacturer may submit a device change to the FDA based on the fact that it now can image another part of the body, has updated software, change the monitor screen, or has added functionality. These updates do not warrant a mandated new facility inspection, which will halt production of already approved products until an FDA inspector completes the new assessment. This would also create a strain on Agency resources, requiring FDA to divert resources to products that have changes with no or limited risk to the patient. FDA should be focusing their resources on known or potential risk. This would benefit not only the FDA, but also patient safety. This will adversely affect innovation in an industry where the U.S. is the global leader, and will prevent patients from having access to the very best available technology.

- As previously mentioned, included among MITA members are small and mid-size companies here in the U.S. that are at the forefront of innovation and development. Many of our small members do not have the resources to pay a $10,000 importer fee as well as an increased registration fee. We are concerned that the increased registration fees will also be a significant burden on all domestic manufacturers. MITA understands the need to fund FDA, but any fees should be targeted at funding the actual inspection of foreign medical device facilities rather than general fees. We look forward to working

with the Committee to come up with a fair and equitable system to increase the FDA's resources while ensuring that imported devices are safe and effective.

- Also referenced earlier, inclusion of component parts in the inspection requirement for medical devices would be duplicative, unnecessary and an imprudent use of funds.

Conclusion

Medical imaging has become integral to best practices across so many disease states and plays a critical role in providing high quality patient care. It is critical that patients have access to innovative medical imaging technology to help fight serious illnesses such as heart disease, cancer, stroke and osteoporosis. We look forward to working with the Committee as it continues to develop this important legislation.

Appendix A: Countries requiring ISO 13485 Certificates

Austria	Ireland	Poland
Belarus	Italy	Portugal
Belgium	Japan	Romania
Brazil	Kyrgyzstan	Russia
Bulgaria	Latvia	Serbia
Canada	Libya	Slovakia
Cyprus	Lithuania	Slovenia
Czech Republic	Luxembourg	South Korea
Denmark	Malaysia	Spain
Estonia	Malta	Sweden
Finland	Mexico	Taiwan
France	Mongolia	Turkey
Germany	Netherlands	Ukraine
Greece	Panama	United Kingdom
Hungary	Peru	Uzbekistan